Guidance Development: Understanding the CDRH Process

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CDRH Process Overview: Level 1 Draft Guidance

- Part I: **Initiation**
- Part II: **Document Development**
- Part III: Internal Guidance ***Review***
- Part IV: External Guidance ***Review***
- Part V: Internal Guidance ***Clearance***
- Part VI: External Guidance ***Clearance***
- Part VII: **Issuance** and Posting

Part I: Initiation

- Guidance Initiation Form (GIF)
  - What is the problem or issue?
  - How will a guidance solve it?
  - What is the urgency?
- GIF Clearance
  - Offices contributing resources
- GIF Approval
  - Deputy Center Director for Policy

Part II: Document Development

- Working Group Formation
  - Subject Matter Experts
  - Good Guidance Practices (GGP) Representative
  - Senior Champion
- Concept Development
- Writing the Guidance

Part III: Internal Guidance Review

GGP Representative

- Branch/Division
- Office(s)
- Deputy Center Director for Policy

(The Working Group usually will need to revise the guidance after management review at any level)

Regulations Staff

Part IV: External Guidance Review

- Office of Chief Counsel (OCC)

  (majority of the time)

  (The Working Group usually will need to revise the guidance after OCC review)

- Other Centers (if applicable)

  (Guidance revision possible)

Part V: Internal Guidance Clearance

GGP Representative

- Branch/Division
- Office(s)
- Deputy Center Director for Policy

Regulations Staff

Part VI: External Guidance Clearance

- Office of Chief Counsel
- Other Centers (if applicable)
- FDA Paperwork Reduction Act Staff
- FDA Office of Policy (if applicable)

- Department of Health and Human Services (if applicable)
- Office of Management and Budget (if applicable)

Part VII: Guidance Issuance

- Publication Process for Federal Register
  - Notice Announcing Availability of Draft Guidance Document
- Guidance Prepared for Web Posting
  - Guidance is Officially Issued on Same Day Notice is Published in Federal Register

What Happens Next?

- Public Comment Period
- Analysis of Public Comments

CDRH Process Overview: Level 1 Final Guidance

- Part II: **Document Development**
  - Draft Guidance Revised Based on Public Comments
- Part III: Internal Guidance ***Review***
- Part IV: External Guidance ***Review***
- Part V: Internal Guidance ***Clearance***
- Part VI: External Guidance ***Clearance***
- Part VII: **Issuance** and Posting

How Long Does It Take?

CDRH's Best Time Frames

Level 1 Guidances

- Drafting a New Guidance
- Analyzing Public Comments
- Finalizing a New Guidance Document

How Can You Participate in Guidance Development?

- Suggest Areas for Guidance Development
- Submit Drafts of Proposed Guidances
- Suggest Withdrawal or Revision of Existing Guidances
- Recommend or Suggest Alternatives to Topics Published in Federal Register

21 CFR 10.115(f)(2-5)

How Can You Participate in Guidance Development?

Before FDA Prepares a Draft of a Level 1 Guidance, FDA Can Seek or Accept Early Input from Individuals or Groups Outside the Agency.

- Hold Public Meetings or Workshops
- Participate in Public Meetings or Workshops

21 CFR 10.115(g)(i)

How Can You Participate in Guidance Development?

- Comment on Draft Guidance
- Comment on Final Guidance at Any Time

Other Guidance Document Sources

- Initial interpretations of statutory requirements
- Reviewer identification of recurring problems or questions in presubmissions
- Issues arising from outside conferences, seminars, workshops
- Technological innovations